K113162
p. 1 of 3

510(k) SUMMARY

This 510(k) summary is provided per the requirements of Section 807.92(c).

Submitted by: Acme Monaco Corporation
75 Winchell Road
New Britain, CT 06052
Phone: 860-224-1349
Fax: 860-827-9982

JUL 2 0 2012

Contact Person: Benjamin Sweeney.
Manager of Device Compliance
Phone: 860-224-1349
bsweeney@acmemonaco.com

Trade Name: Acme Monaco *Slidewire*®

Common Name: Guidewire

Classification Name: Device – Wire, Guide, Catheter

Regulation: Catheter guide wire Per 21 CFR Part 870.1330

Product Code: DQX

Classification: Class II

Date prepared: June 22, 2012

Legally marketed device to which equivalence is claimed:

Terumo Radifocus® Guidewire M Hydrophilic Coated Guidewires, Premarket Notification K863138, and K063372.

5.1 Description of the Device:

The Acme Monaco Hydrophilic Guidewire, hereafter referred to as Acme Monaco Slidewire®, is composed of a Nickel Titanium (aka NiTi or Nitinol) core wire, jacketed with a durable polymer that is receptive to a coating. The polymer resin is blended with Tungsten, a radiopaque metal and affixed to the core wire via adhesive. The jacketed core wire is then coated with a hydrophilic coating. The Acme Monaco Slidewire® can be constructed to various lengths,

diameters and distal configurations, is a single-use device and provided sterile for commercial distribution.

5.2 Scientific concepts that form the basis for the device:

The Acme Monaco Slidewire® has a core wire constructed of Nickel Titanium (aka NiTi or Nitinol). The core wire is coated with a polymer jacket. A radiopaque metal is blended into the polymer resin in order to enhance visibility of the guidewire on medical imaging devices. The polymer jacket is coated with a hydrophilic coating designed to provide a low coefficient of friction when wet, thus enhancing the movement and maneuverability of the device.

5.3 Intended Use of the Device:

The Acme Monaco Slidewire® is intended for use in diagnostic or interventional procedures to assist in directing a catheter to the desired anatomical locations in the coronary or peripheral vasculature.

5.4 Comparison of technological characteristics to legally marked device:

The Acme Monaco Slidewire® is being compared for substantial equivalence against the Terumo Radifocus® Guidewire M, Premarket Notification K863138 and K063372.

The Acme Monaco Slidewire® and the predicate device both contain a Nickel Titanium core. Both products incorporate a polyurethane jacket which covers the core wire. Both the predicate device and the Acme Monaco Slidewire® contain Tungsten that is blended into the polyurethane resin in order to improve visibility on medical images. Both devices employ a hydrophilic coating over the polyurethane jacket in order to provide reduced friction between the medical devices and tissue. Both the predicate device and the Acme Monaco device retain their lubricity over multiple uses during a single procedure. Both devices provide for kink resistance and retain original conformations, even when subjected to tortuous anatomical environments.

The differences between the Acme Monaco Slidewire® and the predicate device lie in the geometric configurations of the distal end of the device, and the method of polymer jacket adherence to the core wire. These differences do not affect the intended use of the Acme Monaco Slidewire®. The Acme Monaco device has been completely tested for biocompatibility in accordance with FAD General Program Memorandum #G95-1, *Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing", May 1, 1995.*

5.5 Performance Testing

Performance testing has been conducted in accordance with FDA guidance document *Coronary and Cerebrovascular Guidewire Guidance, January 1995,* ISO 11070:1998(E), *Sterile single-use intravascular catheter introducers* and ISO 10993-1:2003(E), *Biological evaluation of medical devices – Part 1: Evaluation and testing.* The results of the following performance tests have demonstrated substantial equivalence to the predicate device.

- Tensile Strength
- Torque Strength
- Torqueability
- Tip Flexibility
- Coating Adherence/Integrity
- Catheter Compatibility
- Surface Lubricity
- Dimensional Verification
- Resistance to corrosion

5.6 Biocompatibility Testing

The following biocompatibility testing, performed in accordance with ISO-10993, has been performed on the Acme Monaco *Slidewire®*:

- Cytotoxicity (ISO 10993-5)
- Kligman Maximization/2 Extracts/35 animals/Concurrent (+) controls (ISO 10993-10)
- Intracutaneous Injection/2 extracts (ISO 10993-10)
- Acute Systematic Injection/2 extract (ISO 10993-11)
- Rabbit Pyrogen-Material Mediated (ISO 10993-11)
- Hemolysis Complete (Direct & Indirect) –ASTM (ISO 10993-4)
- In Vitro Hemocompatibility (Direct) (ISO 10993-4)
- Dog Thromboresistance/2 animals (ISO 10993-4)
- Lee & White Clotting Time/Human Blood (Direct) (ISO-10993-4)
- Complement Activation Assay (C3a), Direct Contact (ISO 10993-4)
- Complement Activation Assay (SC5-b-9), Direct Contact (ISO 10993-4)

5.7 CONCLUSIONS

Based on the evaluation of performance and biocompatibility testing, the Acme Monaco Slidewire® is considered to be appropriate for its intended use and performs in an equivalent manner as the Terumo Radifocus Guidewire M. The materials of construction and intended use are virtually identical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 20 2012

Acme Monaco Corp.
Mr. Benjamin Sweeney
Manager, Device Compliance
75 Winchell Road
New Britain, CT 06052

Re: K113162
Trade/Device Name: Acme Monaco Slidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guidewire
Regulatory Class: Class II
Product Code: DQX
Dated: July 17, 2012
Received: July 18, 2012

Dear Mr. Sweeney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K113162

Device Name: Acme Monaco Slidewire™ (Trademark Pending)

Indications for Use: The Acme Monaco Slidewire™ (Trademark Pending) is intended for use in diagnostic or interventional procedures to assist in directing a catheter to the desired anatomical locations in the coronary or peripheral vasculature.

Prescription Use __X__ **AND/OR Over-The-Counter Use** _____

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113162